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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/404,010	09/23/1999	YING LUO	A-68294/DJB/	7948

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EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/404,010	Applicant(s) LUO ET AL.	
	Examiner Janet L. Andres	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 July 2004 has been entered. Claims 25 and 27-33 are pending and under examination in this office action.

Claim Rejections Maintained

2. The rejection of claims 25 and 27-33 under 35 U.S.C. 101 as lacking a specific and substantial utility is maintained for reasons of record in the office actions of 24 March 2004 and 22 September 2003.

Applicant argues that *In re Kirk* is more properly cited as holding that the disclosure of utilities such as "biological activity" or "biological properties" do not meet the requirements of 35 U.S.C. 101, rather than as holding that the disclosure of specific chromosomal localization and consequences are required to provide utility. Applicant argues that the specification asserts a specific utility for diagnosis and prognostic determination of cancer, and that the MPEP does not require a specific chromosomal localization. Applicant argues that "cancer" is a specific disease condition and "detection of Mkinase mutations associated with cancer for diagnosis or prognostic determination" is a specific activity. Applicant further argues that the specification discloses determination of disorders based on mutated Mkinase nucleic acids. Applicant argues

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that Kato et al. affirms these specific utilities. Applicant additionally argues that the specification teaches interaction with Traf4, which has a role in cancer.

Applicant's arguments have been fully considered but have not been found to be persuasive.

Kirk was recited because, as stated in the previous office actions, Applicant's specification provides only general teachings or suggestions. As Applicant indicates, it merely states that Mkinase is useful for diagnosis and prognostic determination of cancer. It does not teach any particular cancer. Cancer is not, as Applicant asserts, a "specific" disease. It is many diseases with many causes, striking many tissues, with many different outcomes. The specification does not teach how Mkinase could be used to diagnose any cancer. It does not teach how Mkinase could be used for prognostic determination of any cancer. No evidence is provided to indicate that there is any alteration in Mkinase that is associated with any form of cancer. The mere assertion that Mkinase might somehow be useful in the diagnosis of cancer does not provide it with a utility. It is not "a sufficiently explicit indication of usefulness of compounds and how to use them" as required by *Kirk*. Clearly, further research was necessary in order to identify how it could actually be used; the invention was not "developed to this point-where specific benefit exists in currently available form" (*Kirk*, quoting *Brenner v. Mason*). Such development was left to Kato et al. As *Kirk* held, it does not matter what the compounds were ultimately found to do: "It is what the compounds are disclosed to do that is determinative here." Neither *Kirk* nor MPEP of course requires disclosure of a chromosomal location. However, the utility provided by Kato et al. stemmed directly from that knowledge. Thus Kato does not "affirm" a utility but rather provides it.

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That Traf4 “has a role” in cancer does not provide a protein that interacts with it with a utility. As stated in the previous office actions, Applicant provides no teachings as to the results of the interaction of Traf4 and Mkinase. There is no indication as to what effect Traf4 has on the activity of Mkinase, or what the consequences of any effect might be. Thus there is, as stated previously, again “no specific benefit in currently available form” associated with this interaction. Clearly, further research would be required to ascertain how Mkinase/Traf4 interaction affects the cell cycle. Applicant’s “reasonable correlation” between Mkinase and cancer does not provide to the public any information as to how to actually use it to affect or diagnose any cancer.

3. The rejection of claims 25 and 27-33 under 35 U.S.C. 112, first paragraph, is maintained for the reasons set forth above and in previous office actions.

Applicant argues that, since the invention has utility, one of skill would know how to use it.

Applicant’s arguments have been fully considered but have not been found to be persuasive. For the reasons set forth above and previously, the invention lacks utility and thus one of skill in the art would not be able to use it.

NO CLAIM IS ALLOWED.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and were finally rejected on the grounds and art of record prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the

submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday, Tuesday, Thursday, Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
14 October 2004



JANET ANDRES
PRIMARY EXAMINER